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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,780	07/15/2003	David White	MPI02-128P1RM	3316

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MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER	
MCGILLEM, LAURA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,780	WHITE ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/15/2003.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to an isolated nucleic acid molecule selected from the group consisting of a nucleic acid molecule comprising a sequence at least 70% identical to the sequence of SEQ ID NO:1 or SEQ ID NO:3; a nucleic acid molecule comprising a fragment of at least 300 nucleotides of the sequence of SEQ ID NO:1 or SEQ ID NO:3; a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO:2; a nucleic acid molecule which encodes a fragment of a polypeptide comprising the amino acid sequence of SEQ ID NO:2 and a nucleic acid molecule encoding an allelic variant of a polypeptide comprising the amino acid sequence of SEQ ID NO:2 wherein the nucleic acid molecule hybridizes to a nucleic acid molecule comprising SEQ ID NO:1, SEQ ID NO:3 or a complement thereof, and host cells containing said nucleic acids classified in class 536, subclass 23.1, for example.

II. Claims 8-9, drawn to an isolated polypeptide selected from the group of, a polypeptide encoded by a nucleic acid molecule comprising a sequence at least 70% identical to the nucleic acids of SEQ ID NO:1, SEQ ID NO:3 or a complement thereof, an allelic variant of a polypeptide comprising SEQ

ID NO:2, and a fragment of a polypeptide comprising SEQ ID NO:2, classified in class 530, subclass 350, for example.

III. Claims 10, drawn to an antibody, classified in class 530, subclass 387.1, for example.

IV. Claim 11, drawn to a method of producing the claimed polypeptide, classified in class 435, subclass 70.1, for example.

V. Claims 12-13, drawn to a method for identifying a compound which binds to a polypeptide, classified in class 435, subclass 4, for example.

VI. Claim 14, drawn to a method to modulate the activity of a polypeptide with a compound, classified in class 435, subclass 4, for example.

VII. Claims 15 and 18, drawn to a method for identifying a compound which modulates the activity of a peptide, classified in class 435, subclass 4, for example.

VIII. Claims 16-17, drawn to a method for identifying a compound capable of treating a metabolic disorder, classified in class 435, subclass 6, for example.

IX. Claim 19, drawn to a method for detecting the presence of a polypeptide, classified in class 435, subclass 4, for example.

X. Claim 20, drawn to a method for detecting the presence of a nucleic acid molecule, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are patentably distinct because each is structurally, biochemically and functionally distinct from the others. The invention of Group I is an isolated nucleic acid molecule comprised of nucleotides, which is structurally and functionally distinct and independent of the invention of Group II, a polypeptide comprised of amino acid residues and the invention of Group III, which is an antibody. The inventions of Groups II and III are not needed for use of the nucleic acid sequence of Group I. The polypeptide of Group II is structurally and functionally distinct and independent of the invention of Group I, a nucleic acid sequence and Group II, an antibody. The inventions of Groups I and III are not needed for use of the polypeptide sequence of Group I. The antibody of Group III is distinct and independent of the invention of Group I, a nucleic acid sequence and Group II, a polypeptide sequence. The antibody of Group III has a distinct biochemical function which does not involve or require the inventions of Groups I and II.

Inventions IV-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are patentably distinct because each of the methods is comprised of different steps and has a different outcome from the other methods. The invention of Group IV is a method of making a polypeptide, which is

patentably distinct from the inventions of Group V, a method for identifying a compound which binds to a polypeptide, Group VI, a method for modulating the activity of a polypeptide,

Group VII, a method for identifying a compound which modulates the activity of a polypeptide, Group VIII, a method for identifying a compound capable of treating a metabolic disorder, Group IX, a method of detecting the presence of a polypeptide in a sample and Group X, a method for detecting the presence pf a nucleic acid molecule in a sample. The outcome of Group IV is a polypeptide, which is distinct from the outcomes of the other groups. The outcome of Group V is the identification of a compound, the outcome of Group VI is modulated peptide activity, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group VIII is an identified compound which treats a disorder, the outcome of Group IX is detection of a polypeptide and the outcome of Group X is the detection of a nucleic acid.

The invention of Group V is a method for identifying a compound which binds to a polypeptide, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group VI, a method for modulating polypeptide activity, Group VII, a method for identifying a compound which modulates polypeptide activity, Group VIII, a method for identifying a compound capable of treating a metabolic disorder, Group IX, a method of detecting the presence of a polypeptide and Group X, a method for detecting the presence of a nucleic acid molecule. The outcome of Group V is the identification of a compound, which is distinct from the outcomes of the other groups.

The outcome of Group IV is a polypeptide, the outcome of Group VI is modulated peptide activity, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group VIII is an identified compound which treats a disorder, the outcome of Group IX is detection of a polypeptide and the outcome of Group X is the detection of a nucleic acid.

The invention of Group VI is a method for modulating the activity of a polypeptide, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group V, a method for identifying a compound which binds to a polypeptide, Group VII, a method for identifying a compound which modulates polypeptide activity, Group VIII, a method for identifying a compound capable of treating a metabolic disorder, Group IX, a method of detecting the presence of a polypeptide and Group X, a method for detecting the presence of a nucleic acid molecule. The outcome of Group VI is modulated peptide activity, which is distinct from the outcomes of the other groups. The outcome of Group IV is a polypeptide, the outcome of Group V is the identification of a compound, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group VIII is an identified compound which treats a disorder, the outcome of Group IX is detection of a polypeptide and the outcome of Group X is the detection of a nucleic acid.

The invention of Group VII is a method for identifying a compound which modulates the activity of a polypeptide, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group V, a method for identifying a compound which binds to a polypeptide, Group VI, a method for modulating polypeptide

activity, Group VIII, a method for identifying a compound capable of treating a metabolic disorder, Group IX, a method of detecting the presence of a polypeptide and Group X, a method for detecting the presence of a nucleic acid molecule. The outcome of Group VII is an identified compound that modulates activity, which is distinct from the outcomes of the other groups. The outcome of Group IV is a polypeptide, the outcome of Group V is the identification of a compound, the outcome of Group VI is modulated peptide activity, the outcome of Group VIII is an identified compound which treats a disorder, the outcome of Group IX is detection of a polypeptide and the outcome of Group X is the detection of a nucleic acid.

The invention of Group VIII is a method for identifying a compound capable of treating a metabolic disorder, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group V, a method for identifying a compound which binds to a polypeptide, Group VI, a method for modulating polypeptide activity, Group VII, a method for identifying a compound which modulates the activity of a polypeptide, Group IX, a method of detecting the presence of a polypeptide and Group X, a method for detecting the presence of a nucleic acid molecule. The outcome of Group VIII is an identified compound which treats a metabolic disorder, which is distinct from the outcomes of the other groups. The outcome of Group IV is a polypeptide, the outcome of Group V is the identification of a compound, the outcome of Group VI is modulated peptide activity, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group IX is detection of a polypeptide and the outcome of Group X is the detection of a nucleic acid.

The invention of Group IX is a method of detecting the presence of a polypeptide, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group V, a method for identifying a compound which binds to a polypeptide, Group VI, a method for modulating polypeptide activity, Group VII, a method for identifying a compound which modulates the activity of a polypeptide, Group VIII is a method for identifying a compound capable of treating a metabolic disorder and Group X, a method for detecting the presence of a nucleic acid molecule. The outcome of Group IX is detection of a polypeptide, which is distinct from the outcomes of the other groups. The outcome of Group IV is a polypeptide, the outcome of Group V is the identification of a compound, the outcome of Group VI is modulated peptide activity, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group VIII is an identified compound which treats a metabolic disorder and the outcome of Group X is the detection of a nucleic acid.

The invention of Group X is a method for detecting the presence of a nucleic acid molecule in a sample, which is patentably distinct from the inventions of Group IV, a method for making a polypeptide, Group V, a method for identifying a compound which binds to a polypeptide, Group VI, a method for modulating polypeptide activity, Group VII, a method for identifying a compound which modulates the activity of a polypeptide, Group VIII, a method for identifying a compound capable of treating a metabolic disorder and Group IX, a method of detecting the presence of a polypeptide. The outcome of Group X is detection of a nucleic acid, which is distinct from the outcomes of the other groups. The outcome of Group IV is a polypeptide, the outcome of Group V is

the identification of a compound, the outcome of Group VI is modulated peptide activity, the outcome of Group VII is an identified compound that modulates activity, the outcome of Group VIII is an identified compound which treats a metabolic disorder and the outcome of Group IX is the detection of a polypeptide..

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product such as claimed can be made in a materially different process of making that polypeptide such as by synthetic polypeptide assembly.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product such as claimed can be used in a materially different process for using that product such as for modulating the activity of the claimed product.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product such as claimed can be used in a materially different process for using that product such as for identification of a compound which modulates the activity of that product.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product such as claimed can be used in a materially different process for using that product such as for detecting the presence of that product in a sample.

Inventions II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product such as claimed can be used in a materially different process for using that product such as for identifying a compound which binds to the claimed product.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (MPEP § 806.05(h)). In the instant case the product such as claimed can be used in a materially different process for using that product such as for *in vitro* translation into a polypeptide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
8/17/2005

DAVID GUZO
PRIMARY EXAMINER